SACHRP Comments on OHRP and FDA Draft Guidance Documents Regarding IRB Transfers

Transfers of research among institutions and IRBs have been an increasingly common occurrence since 1996. In response, OHRP[1] (May 23, 2012) and FDA[2] (June 12, 2012) have released separate guidance documents regarding the transfer of research to another institutional review board (IRB) or institution. SACHRP commends OHRP and FDA for issuing draft guidance on IRB transfers, which will help to provide consistency and quality to this practice. SACHRP has the following comments regarding these draft guidance documents.

First, SACHRP would like to commend the OHRP and FDA for providing these draft guidance documents. They address an important practice among IRBs, and they are flexible documents that will serve to aid IRBs and institutions in conducting transfers of research activities. The documents appropriately stress that the central goal is to provide continuous IRB oversight of ongoing research, which in turn helps to ensure that subjects are adequately protected.

Second, SACHRP encourages the agencies to issue unified joint guidance. SACHRP recommends that when it is not practical to issue a joint guidance, the agencies issue guidance documents that are as similar as possible in content. In the current draft guidance documents, there are areas where one document is more specific than the other without obvious reasons for the dissimilarities. For instance, the OHRP document provides more detail about the steps to be taken regarding IRB transfers within an institution.

Third, SACHRP recommends that OHRP adopt the approach that FDA has taken on "Transfer of IRB Oversight between Two IRBs in the Same Institution" (Section IV. A). The FDA approach is less complex and equally provides flexibility and guidance on human subject protection, without unduly burdening investigators, IRBs and institutions. This approach would also create closer conformance between the two documents.

Fourth, SACHRP recommends that the table in the OHRP scenario 3 should be incorporated into text format as needed because it is difficult to read and because it is largely repetitive of existing text. This section could also be reduced in length similar to the FDA guidance document.

SACHRP notes that both draft documents recommend the use of a written agreement and suggests that IRBs, not institutions, are responsible for setting up such agreements. Agreements between institutions are generally an institutional responsibility and decision, rather than an IRB responsibility and decision. Both documents should better reflect that this is an institutional responsibility rather than an IRB responsibility.

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[1] "Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution," online at http://www.hhs.gov/ohrp/newsroom/rfc/pdftransferdraftdoc.pdf.

[2] "Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another Institutional Review Board," online at http://www.gpo.gov/fdsys/pkg/FR-2012-06-12/pdf/2012-14295.pdf.

Fifth, while recognizing that the use of a written agreement and the suggested actions are qualified with the term "as appropriate," SACHRP recommends that OHRP and FDA rephrase the language about the written agreement to stress that the agreement outlines the plan for how the transfer will occur and provides criteria for determining that the transfer is complete. It is often not feasible or necessary to address all of the eight recommended actions in advance in a written agreement, as many of them will be case-dependent. SACHRP recommends that the agencies instead say, "When transferring IRB review and oversight of research projects from one IRB to another IRB, OHRP recommends that a plan for the transfer process be documented in a written agreement between the original and receiving IRBs, if appropriate. The agreement should address how the IRBs document the following eight actions, as appropriate. We describe each of these actions in more detail below."

Sixth, SACHRP also believes that the parenthetical "Note" in the "Introduction" section of the OHRP draft should be revised to specifically to change "may not" to "normally will not", as follows: "[Note: OHRP recognizes that for transfers of oversight between IRBs at the same institution, a written agreement *normally will* not be necessary as the process may be addressed by the institution's established procedures (assuming all appropriate steps as identified below are covered). However, the transfer should be appropriately documented, or addressed in written policies.]"

Seventh, when research projects are transferred from an institution, consideration should be given to local law. IRBs and institutions often are required by state law or institutional policy to limit the access to their records and may only share records in circumstances where the requesting party has a regulatory or legal right to review them.

Eighth, SACHRP recognizes that privacy issues commonly arise in the transfer of data and documents to a new entity. These concerns arise, for example, from HIPAA, state medical privacy laws, state genetic privacy laws, and federal drug and alcohol treatment record laws. SACHRP recommends that the guidance address authorization and waiver considerations, and how entities can proactively plan for potential transfers from a privacy perspective. SACHRP recommends that OHRP and FDA consider inclusion of Office for Civil Rights (OCR) input on HIPAA concerns.

Finally, SACHRP notes that in regards to action six of the guidance documents, it is suggested that there are many ways to notify previously enrolled subjects of the change of IRB, including use of a postcard. For many types of research, use of a postcard would reveal potentially private information to postal clerks, family members, etc. SACHRP suggests that the term "letter" rather than "postcard" would be preferable.

In closing, SACHRP commends OHRP and FDA for issuing draft guidance on IRB transfers, which will help to provide consistency and quality to this activity.